



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/965,708 | 09/26/2001 | Markus Heil | Le A 34 813 | 8172 |

7590 03/31/2003

Jeffrey M. Greenman
Vice President, Patents and Licensing
Bayer Corporation
400 Morgan Lane
West Haven, CT 06516

| |
|----------|
| EXAMINER |
|----------|

WRIGHT, SONYA N

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1626

DATE MAILED: 03/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,708

Applicant(s)

HEIL ET AL.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _ is/are allowed.
- 6) ☐ Claim(s) 1,3-5 and 12 is/are rejected.
- 7) ☒ Claim(s) 2 and 9-11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1626

DETAILED ACTION

This is a response to Applicant's remarks filed 1-21-03. Claims 1-7 and 9-12 are pending in this application.

The rejections under 35 U.S.C. 102 and 103 have been maintained for the reasons of record.

The rejections under 35 U.S.C. 112 first paragraph and 112 second paragraph have been overcome with Applicant's amendments.

The objection to claims 3 and 4 have been withdrawn. The objection to claim 7 is moot because claim 7 has been restricted out.

Election/Restrictions

Claims 6 and 7 have been restricted out. The claims were originally presented as product by process claims. The claims have been amended and are now not claimed as they were originally presented, therefore they have been withdrawn from consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by STN

International® CAPLUS Database, Accession No. 1991:514130; Fujisawa

Pharmaceutical Co., Ltd., Japanese Patent JP03056431 (1991), abstract.

Art Unit: 1626

Applicant claims phenoxyphenyl alkanesulphonates which are useful in treating neurodegenerative disorders. JP03056431 teaches biphenyl compounds which are useful as analgesics, antirheumatics, and blood platelet promoters. JP03056431 teaches the instant claims when, in the instant claims, R1 is hydrogen, R2 is nitro, R3 is methyl or trifluoromethyl, R4 is hydrogen, and A is oxygen. See RN 135209-90-4 and RN 135210-08-1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating

obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-5, are rejected under 35 U.S.C. 103(a) as being unpatentable over STN International® CAPLUS Database, Accession No. 1991:514130; Fujisawa Pharmaceutical Co., Ltd., Japanese Patent JP03056431 (1991), abstract.

Determination of the scope and content of the prior art (MPEP §2141.01)

JP03056431 teaches biphenyl compounds which are useful as analgesics, antirheumatics, and blood platelet promoters. JP03056431 teaches the instant claims when, in the instant claims, R1 is hydrogen, R2 is nitro, R3 is C4-C7 alkyl which may be substituted one or more times by fluorine or chlorine, R4 is hydrogen, and A is oxygen. See species examples RN 135209-90-4 and RN 135210-08-1.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

In claim 3, there is a hydrogen atom in position 4 of the phenyl ring substituted by R1 and R2. JP03056431 teaches a positional isomer of the compounds of claim 3 in examples RN 135209-90-4 and RN 135210-08-1. In JP03056431 there are hydrogens in positions 2, 3, 5, and 6 and not in position 4, as in instant claim 3.

In claim 4, R1 and R2 occupy positions 2 and 3 on the phenyl ring. JP03056431 teaches a positional isomer of the compounds of claim 4. In JP03056431, in examples RN 135209-90-4 and RN 135210-08-1, R2 is nitro and it occupies position 4, not position 2 or 3, as in instant claim 4.

In claim 5, A is in position c of the benzene radical. JP03056431 teaches a positional isomer of the compounds of claim 5. In JP03056431, in examples RN 135209-90-4 and RN 135210-08-1, nitrogen (which corresponds to A in the instant claims) is in the 4-position on the phenyl, not in the c position as in instant claim 5.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

One of ordinary skill in the art would be motivated to prepare the instant compounds because nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Applicants, since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 12 is directed to "organic diseases". The specification does not reasonably provide enablement for the instantly claimed compounds.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. Prior arts do not indicate which "organic diseases" may be treated by the instant compound. There is little predictability in the art of which modifications may be made to the instant compound which would retain its ability to be useful in treating "organic diseases". The term "organic diseases" may encompass a great number of compounds however, without some guidance as to what changes may be made to the compound of formula I, there would be little predictability in making and/or using the instant invention to treat "organic diseases". The level of ordinary skill in the art is high. The specification provided limited guidance (see page 17, line 6) and no working examples for what "organic diseases" may be treated by the claimed invention. The

Art Unit: 1626

skilled artisan would have a numerous amount of modifications to perform in order to use the instant compound in treating organic diseases. Undue experimentation would be required to use the instant compounds as claimed.

This rejection can be overcome by Applicant specifying which "organic diseases" are treated by the instant invention. Any diseases listed must be supported in the specification.

Claim Objections

Claims 2 and 9-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 1-21-03 have been fully considered but they are not persuasive regarding the rejections under 35 U.S.C. 102 and 103. Regarding the rejection under 35 U.S.C. 102, Applicant argues that since JP3056431 does not teach substitution at any available carbon on the phenyl, JP03056431 does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. 102(b) has not been established.

However, the instant genus in claim 1 embraces a plethora of species. JP03056431 teaches two species which consist of each and every limitation of two of the species which fall under the genus of the instant claims. It is not necessary for a prior art reference to teach every species that falls under Applicant's genus in order for

the reference to be used in a 102 rejection. If a prior art reference teaches at least one species which falls under the genus of the instant claims, and if the publication or issue date of the reference is more than 1 year prior to the effective filing date of the application, the reference qualifies as prior art under 35 U.S.C. 102(b). Therefore, the rejection under 35 U.S.C. 102(b) is proper.

Regarding the rejection under 35 U.S.C. 103, Applicant argues that "JP03056431 does not teach or suggest substitution at any available carbon on the phenyl". Further, Applicant argues that "based on the disclosure of JP03056431, one skilled in [the] art would assume that substitutions at the 4-position on both phenyl rings are critical for biological activity. One would not expect that substitutions could be made at any position on the phenyl ring, and the compound would still possess biological activity. Thus, Applicants do not see where there is a suggestion to make the compounds of the present invention. Even if there were, nothing suggests that if such compounds were made, the resulting compounds would be successful."

However, it would be obvious to prepare compounds similar to those of JP03056431 in the expectation that they would be useful in analgesics, antirheumatics, and blood platelet promoters.

In claim 3, there is a hydrogen atom in position 4 of the phenyl ring substituted by R1 and R2. JP03056431 teaches a positional isomer of the compounds of claim 3 in examples RN 135209-90-4 and RN 135210-08-1. In JP03056431 there are hydrogens in positions 2, 3, 5, and 6 and not in position 4, as in instant claim 3.

In claim 4, R1 and R2 occupy positions 2 and 3 on the phenyl ring. JP03056431 teaches a positional isomer of the compounds of claim 4. In JP03056431, in examples

RN 135209-90-4 and RN 135210-08-1, R2 is nitro and it occupies position 4, not position 2 or 3, as in instant claim 4.

In claim 5, A is in position c of the benzene radical. JP03056431 teaches a positional isomer of the compounds of claim 5. In JP03056431, in examples RN 135209-90-4 and RN 135210-08-1, nitrogen (which corresponds to A in the instant claims) is in the 4-position on the phenyl, not in the c position as in instant claim 5.

One of ordinary skill in the art would be motivated to prepare the instant compounds because nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Applicants, since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950). Further motivation is given by the two species examples of the instant claims which are taught by JP03056431.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Art Unit: 1626

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

March 25, 2003